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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,789	06/12/2000	John J. Machalonis	7760-012	5233
20583	7590	05/16/2006	EXAMINER PARKIN, JEFFREY S	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/591,789	<b>Applicant(s)</b> MARCHALONIS ET AL.	
	<b>Examiner</b> Jeffrey S. Parkin, Ph.D.	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                               |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/15/06</u> . | 6) <input type="checkbox"/> Other: _____                                                |

Serial No.: 09/591,789  
Applicants: Marchalonis, J. J., et al.

Docket No.: 7760-012  
Filing Date: 06/12/00

### Detailed Office Action

#### *Status of the Claims*

Acknowledgement is hereby made of receipt and entry of the communication filed 15 February, 2006. Claims 7 and 24-26 are currently under examination.

#### *37 C.F.R. § 1.98*

The information disclosure statement filed 15 February, 2006, has been placed in the application file and the information referred to therein has been considered.

#### *35 U.S.C. § 112, Second Paragraph*

The previous rejection of claims 7, 24, and 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

#### *35 U.S.C. § 103(a)*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering

patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 7 and 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Liang et al. (1998). Liang and colleagues disclose the administration of a human TCR V $\beta$ 8.1 peptide (NH<sub>2</sub>-CKPISGHNSLFWYRQT-COOH; see MATERIALS AND METHODS, *Peptides*, p. 463), which is identical to the currently claimed peptide, to C57BL/6 mice that were free of infection with an immunodeficiency-type retrovirus. Administration of this peptide resulted in increased production of Th1 cytokines (e.g., see Figure 3) and decreased production of Th2 cytokines (e.g., see Figures 5 and 6). Thus, this teaching meets all of the claimed limitations with one exception, it does not disclose the administration of this human peptide to humans to accomplish the same effect. However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to administer the aforementioned peptides to humans to combat cytokine irregularities associated with ageing, as disclosed by Liang and associates. Moreover, a reasonable expectation of success was also present since the C57BL/6 murine model represents a useful model for assessing the effectiveness of such peptides.<sup>1</sup>

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<sup>1</sup> Applicants also noted in the communication dated 27 April, 2005, that "the mouse model is an art accepted model for testing compounds for their effects in humans".

### ***Additional Prior Art***

The following additional prior art, which was not relied upon in the office action, is considered germane to applicant's disclosure:

- Liang, B., et al., 1996, T-cell receptor dose and the time of treatment during murine retrovirus infection for maintenance of immune function, *Immunol.* 87:198-204.

- Liang, B., et al., 1996, Effects of vaccination against different T cell receptors on maintenance of immune function during murine retrovirus infection, *Cell. Immunol.* 172:126-134.

- Watson, R. R., et al., 1995, T cell receptor V $\beta$  complementarity-determining region 1 peptide administration moderates immune dysfunction and cytokine dysregulation induced by murine retrovirus infection, *J. Immunol.* 155:2282-2291.

### ***Correspondence***

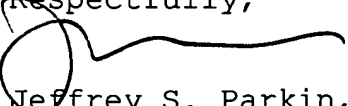
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized

Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

14 May, 2006